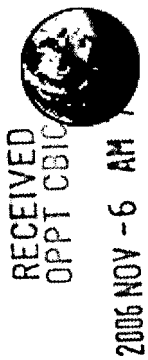

Richard Denison
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10/11/2006 07:01 PM

To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, NCIC HPV@EPA, Karen Boswell/DC/USEPA/US@EPA, Cpma@cpma.com MTC@mchsi.com, Karen Florini
cc: <KFlorini@environmentaldefense.org>, Richard Denison <rdenison@environmentaldefense.org>
bcc:
Subject: Environmental Defense comments on C.I. Pigment Red 48 (Calcium), C.I. Pigment Red 48 (Barium) and C.I. Pigment Red 52 (Calcium)

(Submitted via Internet 10/12/06 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Cpma@cpma.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **C.I. Pigment Red 48 (Calcium), C.I. Pigment Red 48 (Barium) and C.I. Pigment Red 52 (Calcium).**

The Monoazo and Related Pigments Committee of the Color Pigments Manufacturers Association, Inc., in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted a test plan and robust summaries for C.I. Pigment Red 48 (Calcium), C.I. Pigment Red 48 (Barium) and C.I. Pigment Red 52 (Calcium); CAS#s 7023-61-2, 7585-41-3, and 17852-99-2, respectively. As stated in this submission, these pigments have very similar structures. They could and should be considered together as a chemical category; however, consideration as a category is not proposed in this submission.

Both the test plan and robust summaries are poorly written and provide minimal information. Further, data developed for a somewhat structurally related chemical, C.I. Pigment Red 57, is proposed as surrogate to address many of the SIDS elements for these pigments. However, unlike the pigments considered, C. I. Pigment Red 57 does not contain a chlorine atom. It is well-established that chlorination may very significantly alter the chemical/physical properties, persistence and toxicity of a chemical. Thus, data developed for C.I. Pigment Red 57 should not be considered an appropriate surrogate for data for C.I. Pigment Red 48 and 52.

Specific Comments:

1. D & C Pigment Red 7 is mentioned as a surrogate along with C.I. Pigment 57 in the test plan, under "Rationalization for Use of Surrogate Data" as well as in the robust summaries. However, no structural formula was provided for D & C Pigment Red 7. We are aware that pigments may be known by different names depending on their use and that the designation "D & C" may indicate a different use of the same pigment. However, the relationship between pigments 57 and 7 and the chemicals considered here should be clearly stated.

2. In the test plan and robust summaries, the melting point is said to be from a "reputable journal"; however, no reference to this journal is provided. Also, though two of the pigments considered here are calcium or barium salts of C.I. Pigment 48, one of the melting points given for these compounds was determined with the manganese salt. Use of data for the manganese salt would seem an appropriate surrogate, but it is not mentioned as a source of surrogate data.
3. Our review of one study described in the robust summary to address the SIDS element for acute toxicity indicates that the purity of the chemical tested, the rat strain and the dose were unknown, and, of course, this study was not conducted under GLP, yet the study was considered by the sponsor to be "reliable with restrictions". We do not agree that such a study can be given much credibility at all.
4. The experimental design of one study described in the robust summaries indicates the test animals were exposed to C.I. Pigment Red 57; however, the results of that study are reported for D & C Pigment Red 7. This should be corrected or explained.
5. The robust summary for developmental toxicity provides no information regarding species, dose, or results other than to state maternal toxicity was observed.
6. The second sentence of the test plan describing Biodegradation is incomplete.

In summary, both the test plan and robust summaries of this submission are poorly written and provide minimal information regarding C.I. Pigment Red 48 (Calcium), C.I. Pigment Red 48 (Barium) and C.I. Pigment Red 52 (Calcium). Further, most data described are for a chemical, C. I. Pigment Red 57, which is not an appropriate surrogate. Therefore, this submission does not meet the requirements of the HPV Challenge.

Thank you for this opportunity to comment.

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